

Canadian Update on Surgical Procedures (CUSP) Urology Group consensus for intraoperative hemostasis during minimally invasive partial nephrectomy

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Cite as: Cheung DC, Wallis CJD, Possee S, et al. Canadian Update on Surgical Procedures (CUSP) Urology Group consensus for intraoperative hemostasis during minimally invasive partial nephrectomy. *Can Urol Assoc J* 2020;14(9):E387-93. <http://dx.doi.org/10.5489/cuaj.6579>

Published online June 9, 2020

Abstract

Introduction: Partial nephrectomy remains the gold standard in the management of small renal masses. However, minimally invasive partial nephrectomy (MIPN) is associated with a steep learning curve, and optimal, standardized techniques for time-efficient hemostasis are poorly described. Given the relative lack of evidence, the goal was to describe a set of actionable guiding principles, through an expert working panel, for urologists to approach hemostasis without compromising warm ischemia or oncological outcomes.

Methods: A three-step modified Delphi method was used to achieve expert agreement on the best practices for hemostasis in MIPN. Panelists were recruited from the Canadian Update on Surgical Procedures (CUSP) Urology Group, which represent all provinces, academic and community practices, and fellowship- and non-fellowship-trained surgeons. Thirty-two (round 1) and 46 (round 2) panellists participated in survey questionnaires, and 22 attended the in-person consensus meeting.

Results: An initial literature search of 945 articles (230 abstracts) underwent screening and yielded 24 preliminary techniques. Through sequential survey assessment and in-person discussion, a total of 11 strategies were approved. These are temporally distributed prior to tumor resection (five principles), during tumor resection (two principles), and during renorrhaphy (four principles).

Conclusions: Given the variability in tumor size, depth, location, and vascularity, coupled with limitations of laparoscopic equipment, achieving consistent hemostasis in MIPN may be challenging. Despite over two decades of MIPN experience, limited evidence exists to guide clinicians. Through a three-step Delphi method and rigorous iterative review with a panel of experts, we ascertained a guiding checklist of principles for newly beginning and practicing urologists to reference.

Introduction

Partial nephrectomy remains the gold standard in the management of small renal masses (cT1a),¹⁻⁴ and its use has been steadily increasing, particularly when performed by minimally invasive approaches.^{5,6} However, minimally invasive partial nephrectomy (MIPN) has a steep learning curve,⁷ leading to considerable technical and procedural variation.⁸⁻¹⁰ Time-efficient yet effective hemostasis is critical during these procedures, as perioperative hemorrhage can lead to morbidity,

increased costs, and must be carefully balanced with the risk of renal injury due to prolonged warm ischemia.^{11,12} The true role and benefit of hemostatic agents is unclear. Likely as a result, there is significant variation in the use of and type of hemostatic agents employed during MIPN. Acknowledging the relative scarcity of robust clinical evidence, we aimed to collate the opinions of expert academic and community urologists performing minimally invasive partial nephrectomy (MIPN) to achieve a consensus statement for best practices in achieving intraoperative hemostasis.

The Delphi method has been previously well-described as a method of achieving expert consensus.^{13,14} It is a systematic approach to garner expert consensus opinion through sequential “rounds” involving the proposal of techniques and strategies, refinement of these guiding principles, and discussion to converge upon an accepted response. We have previously used this iterative process in determining quality indicators in renal cell carcinoma care.¹³ With this approach and an expert working group of Canadian minimally invasive urologic surgeons, we sought to determine a set of evidence-based and actionable guiding principles for urologists to approach hemostasis during MIPN without compromising warm ischemia or oncological surgical margins.

Methods

The Delphi method

The three-step Delphi method of consensus was used to achieve expert agreement on best practices for hemostasis in MIPN. A systematic literature search to identify potential techniques and strategies was completed, followed by a three-round iterative approach (surveys and final group meeting) to achieve consensus. The MIPN procedure was divided into three distinct potential timeframes to examine procedural variability and developing consensus in the study: 1) prior to tumor resection; 2) during tumor resection; and 3) during renorrhaphy and following vascular unclamping.

Panel selection

Panelists were recruited from members of the Canadian Update on Surgical Procedures (CUSP) Urology Group, which meets biannually for scientific and technical exchanges. CUSP members represent all provinces, academic and community practice settings. Overall, panelists had been in practice for a mean of 11 years (range 2.5–21 years) and performed an average case volume of 35 MIPN (range 10–100) per year. Most panelists were fellowship-trained urologic surgeons. Panelists agreed to participate after project presentation at the 2017 CUSP meeting.

Literature search

We conducted a search of the literature using the search terms “partial nephrectomy” AND (“robotic” or “laparoscopic” or “minimally invasive”) AND (“hemostasis” or “hemorrhage” or “bleeding” or “blood loss” or “hemostatic agents”) using MEDLINE for relevant publications between January 2000 and August 2017. English-language publications that were original research and review articles were screened for relevance to hemostasis in MIPN, including their manuscript references for completeness (DC, SP, and RS). Articles were excluded if they did not include a MIPN cohort, were editorials or abstracts only, did not include human subjects, did not discuss a hemostatic technique or agent, and/or did not include hemostasis as an outcome. A non-duplicated list of best principles for preliminary inclusion was tabulated for each timeframe listed. Review of the articles (DC, SP, and RS) and of the subsequent suggested techniques (all authors) was completed prior to round 1.

Rounds 1 and 2

Following literature search, principles that were identified as relevant to each of “prior to tumor resection,” “during tumor resection,” and “during renorrhaphy” were reviewed by the authors, and a list of principles was then distributed via email mailing list to the CUSP membership (round 1: 32 panellists; round 2: 46 panellists). These were ranked according to Likert scale from 1 (not at all relevant) to 7 (extremely relevant) for achieving hemostasis in MIPN based on their clinical experience. All responses were recorded and graphed to demonstrate the frequency of distribution per item and ranking.

A score of 4 was defined as neither relevant nor irrelevant within the survey and did not count towards approval or rejection of a proposed technique. Approval and advancement required over 50% agreement of adopting the item (Likert score 5, 6, 7). Furthermore, a free text option was available at each stage for participants to suggest additional principles that had been omitted or overlooked, and to provide general comments. These were then carefully reviewed by the authors (DC and RS). Once duplicate suggestions and those not pertaining directly to hemostasis were excluded, free text suggestions were incorporated into the next survey iteration with the collated results from existing principles. In some cases, principles of hemostasis were combined for conciseness and clarity. A new questionnaire was then designed with the updated principles. This process was repeated following the second round.

Round 3

An in-person meeting was planned for November 2017 for third-round review of the suggested principles. This was

attended by 22 panelists, as defined above. At this meeting, the results from rounds 1 and 2 were collated and presented. This included the principles that had advanced through the screening, as well as justification for those which had not. Panelists were offered the opportunity to directly exclude any principles they felt were not relevant via group discussion. At this meeting, it was felt that there should not be prioritization of principles, as one may become more or less clinically relevant in any given case and subject to the clinical expertise of the operating surgeon.

In total, 32 panelists submitted responses to round 1 of the survey (28 fully completing the survey), 46 panelists submitted responses to round 2 of the survey (35 fully completing the survey), and 22 individuals attended the in-person meeting for round 3. The full modified Delphi approach and the results from each round are summarized in Fig. 1.

Manuscript review

The draft manuscript was then reviewed over email distribution, as well as at the CUSP Urology Group biannual meeting in November 2019 for final approval. This was attended by 18 CUSP panelists. Minor wording/clarity changes were made, with no content changes to the final guiding principles.

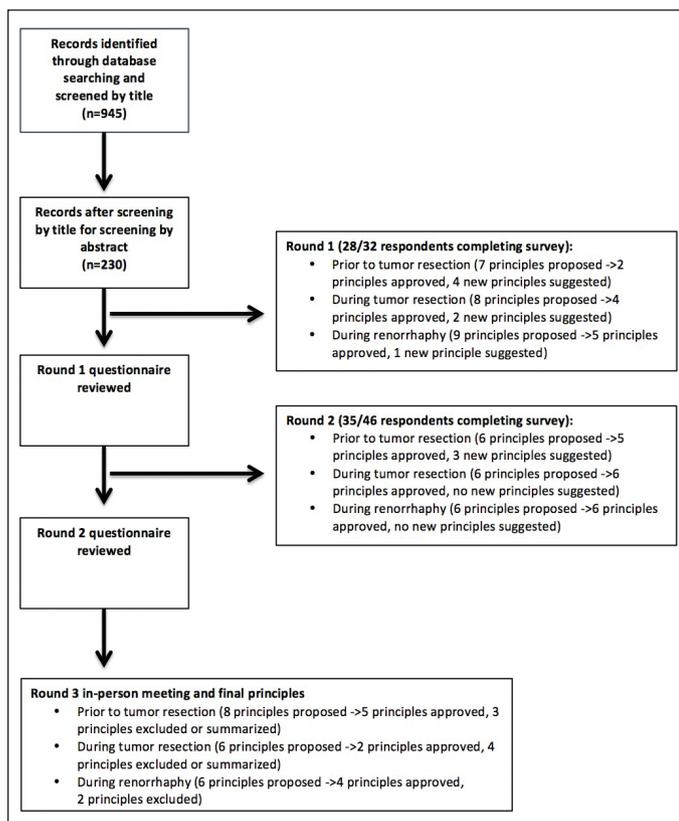


Fig. 1. Modified Delphi technique process.

Results

A total of 945 articles were identified as having potential relevance to hemostasis and MIPN. All articles were reviewed by the authors by title, and 230 were further screened for hemostatic principles by abstract. Of these, an initial 24 techniques of achieving hemostasis in MIPN were tabulated. These were distributed into seven techniques prior to tumor resection, eight techniques during tumor resection, and nine techniques during renorrhaphy. These preliminary techniques and strategies were then distributed to expert urologists in the first round (Supplementary Tables 1A, 1B).

Of the initial 24 principles, 11 were accepted and advanced to the second round and 13 were rejected by over 50% agreement, while seven new principles were proposed via free text by the group (Fig. 1). The authors then reviewed all the results prior to the creation of the second-round survey.

For the second round, 17/18 principles were approved, one was rejected, and three principles were newly suggested (Supplementary Tables 2A, 2B). These results were again reviewed and summarized in a similar fashion to the first round before advancing to the final in-person meeting.

All the final guiding principles were reviewed and discussed at the in-person meeting in round 3 (Table 1). These are distributed across prior to tumor resection (five principles), during tumor resection (two principles), and during renorrhaphy (four principles). The remainder of the principles were merged for clarity or excluded directly at the time of the meeting.

Discussion

At this time, despite nearly two decades of MIPN experience, very limited evidence exists to guide clinicians regarding techniques to optimize hemostasis during MIPN. We rigorously reviewed techniques for achieving hemostasis in MIPN using a three-step Delphi method, including a geographically diverse panel of Canadian experts in minimally invasive surgery from academic and community practice settings (CUSP). By systematically probing these techniques and strategies through an iterative approach, members of the survey and panel could provide detailed input at each stage regarding the inclusion of relevant techniques and the exclusion of those that were not. We outlined multiple timeframes within MIPN (prior to tumor resection, during tumor resection, and during renorrhaphy) to further improve the applicability and ease of utility of the final metrics. This will allow surgeons to quickly reference them as an evidence-based, concise, and actionable checklist for their approach.

In total, 24 principles were initially suggested from the literature search and an additional 10 were proposed during surveys, with 11 principles ultimately achieving over-

Table 1. Final approved considerations for achieving hemostasis in minimally invasive partial nephrectomy**Final approved techniques and strategies****Prior to tumor resection**

1. Discontinuation of therapeutic anticoagulation, excluding ASA for high-risk individuals
2. Ensuring adequate renal mobilization and hilar dissection
3. Consider selective arterial clamping based on anatomy
4. Targeting adequate pneumoperitoneum pressure
5. Pre-clamp time out:
 - a. Prior preparation of all sutures including safety sutures ahead of time (i.e., number, bolster, type, length)
 - b. Availability of hemostatic agent ready for use
 - c. During robotic partial nephrectomy, ensure trocars are visible and tract is clear to facilitate instrument change if needed

During tumor resection

1. Reducing distance of resection margin from tumor (e.g., staying closer to the tumor)
2. Assistant or surgeon to apply pressure on bleeding areas

During renorrhaphy

1. Consider using a barbed stitch instead of traditional absorbable suture for hemostatic running stitch
2. Consider the use of gelatin thrombin agents if available
3. Placing clips (e.g., sliding clip technique) over knot tying of sutures
4. Early unclamping to identify and suture ligate significant arterial bleeding prior to apposition of the parenchyma

ASA: American Society of Anesthesiologists.

all group consensus through all three iterations. Of these, the majority of approved strategies (7/11: discontinuation of therapeutic anti-coagulation, selective clamping based on anatomy, targeting pneumoperitoneum, reducing the resection margin to tumor, use of a barbed stitch, use of gelatin-based sealant, and placing clips instead of knot tying sutures) were maintained across all rounds, highlighting the robust nature of the initial literature review and consistency throughout the selection process.

We recognize that different provinces within Canada may have conflicting availability of hemostatic agents. Of note, gelatin thrombin agents were specifically identified within the panel over fibrin sealants, oxidized cellulose polymer, and hemostatic patch, but may represent the panel's familiarity with these agents. In real-world application, in the absence of randomized evidence stating superiority, this may depend on the operator's experience. Ultimately, within this area, there continues to be limited evidence towards their efficacy outside of animal models, single-center or single-surgeon small retrospective case series, or only with selective agents/techniques,¹⁵⁻²³ and this study is the first to provide an approach on the use of these agents through the experience of expert urologic surgeons (CUSP). In addition, individuals who are fellowship-trained vs. not, in academic vs. community practice, and in teaching vs. non-teaching

centers may also have differing opinions towards the optimal techniques in hemostasis. Throughout our surveys and panel discussion, we were conscientious to include surgeons representative of a variety of practice settings where possible (although the majority were fellowship-trained).

A few principles were directly excluded during the in-person meeting. In particular, the authors would like to highlight three of the principles that did not advance to the final consensus document: "early clipping of identifiable blood vessels," "unclamping the renal vein if bleeding was encountered," and "increasing the pneumoperitoneum with bleeding." In particular, the members of the panel stressed that the "early clipping of identifiable blood vessels" and "unclamping the renal vein in the occurrence of bleeding" were important, but represented basic surgical principles that did not require special mention so as to not dilute the quality of the remaining strategies. "Increasing the pneumoperitoneum" was felt to be captured within "achieving adequate pneumoperitoneum" prior to tumor resection.

We believe that these methods represent an excellent foundational basis towards achieving hemostasis in MIPN. They are helpful principles designed to aid newly starting and currently practicing urologic surgeons but are not an exhaustive or mandatory. Additionally, these principles may also have extended applications in surgical education, standardization, quality-care benchmarking, and/or inclusion into surgical safety checklists in the future. Ultimately, while these guiding principles highlight important components of achieving hemostasis in MIPN, surgical planning must remain individualized to the tumour (i.e., nephrometry score), the patient, and the surgeon.

Limitations

There are several limitations in using the Delphi technique to achieve consensus. Although the iterative process is designed to generate and refine the proposed principles as much as possible, this remains limited by the composition of the panel. Our panel was chosen to represent diverse practice settings; however, some hemostatic agents were not available to all panel members and may not be accessible within your own locale. More vocal members of the panel also have the opportunity to influence the results of the discussion over other members, although this was not seen during our in-person meeting. Furthermore, given that our results and voting were anonymous in the initial surveys, this decreased the risk of bias from this metric.

Conclusions

Achieving hemostasis in MIPN can be a challenging task and limited evidence exists to date to guide clinicians. Through a three-step Delphi method and rigorous iterative review

with a panel of experts, we ascertained a guiding checklist of principles to which newly beginning and practicing urologists can refer. Overall, the goal of this study is to identify commonly accepted principles of hemostasis to improve the quality of MIPN that is performed across Canada.

Competing interests: Dr. Deklaj has been a consultant for TerSera. Dr. Gotto has been an advisory board member for and received honoraria from Amgen, Astellas, Bayer, Janssen, Merck, Roche, and Sanofi; and has participated in clinical trials supported by Amgen, Astellas, AstraZeneca, Bayer, Janssen, Myovant, and Pfizer. Dr. Izard has been an advisory board member for and received consulting fees from AbbVie, Astellas, Ferring, Janssen, and Sanofi; and has participated in clinical trials supported by Astellas, AstraZeneca, and Merck. Dr. Jain has participated in clinical trials supported by CMX. Dr. Kawakami has been a procter for Minogue Medical and is a stockholder in and advisor for Vibe Bioscience. Dr. Lee received honoraria for a lecture from Baxter. Dr. Richard has been an advisory board member for BMS and Sanofi; a speakers' bureau member for Abbvie, Amgen, Astellas, Ferring, and Janssen; and has participated in clinical trials supported by Calithera and Lidds Pharma. Dr. Rowe has participated in an advisory board meeting for Acerus and has received honoraria from Sanofi. Dr. St. Martin has received speaker honoraria from Pfizer. Dr. Yang has been an advisory board member for and received speaker fees from Allergan, Astellas, Pfizer, and Sanofi. Dr. Zorn has received honoraria as a procter/Greenlight lecturer for Boston Scientific; and has participated in clinical trials supported by Procept Biorobotics. Dr. Kapoor has been an advisory board member for and participated in clinical trials supported by Amgen, Astellas, Janssen, GSK, Novartis, Pfizer, and Sanofi. Dr. Finelli has been an advisory board member for Abbvie, Astellas, Bayer, Ipsen, Janssen, Sanofi, and TerSera; and has participated in clinical trials supported by Astellas, Bayer, and Janssen. The remaining authors report no competing personal or financial interests related to this work.

This paper has been peer-reviewed

Support: Baxter International provided organizational support and sponsorship to attend the CUSP meeting, wherein meetings related to this specific study were held. Baxter had no role within the selection process of iterative surveys, or in the final consensus discussion, drafting, or critical review of the final manuscript.

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Supplementary Table 1A. Suggested techniques and strategies from round 1

Prior to tumor resection	During tumor resection	During renorrhaphy
<ol style="list-style-type: none"> 1. Clamping artery + vein vs. artery alone 2. Controlled hypotension 3. Robotic vs. lap 4. Discontinuation of anti-platelet agents 5. Antifibrinolytics 6. En-bloc clamping vs. bulldogs 7. Intraoperative doppler for flow <p>Newly suggested:</p> <ul style="list-style-type: none"> • Renal mobilization and hilar dissection • Selective arterial clamping • Adequate pneumoperitoneum • Prior suture preparation 	<ol style="list-style-type: none"> 1. Enucleation 2. Early clipping of vessels 3. Reducing resection margin to tumor (staying close to tumor) 4. Increasing pneumoperitoneum 5. Electrocautery of resection bed 6. Electrocautery resection 7. Argon beam coagulator 8. Ultrasonic/harmonic <p>Newly suggested:</p> <ul style="list-style-type: none"> • Assistant to apply pressure • Unclamping vein if bleeding 	<ol style="list-style-type: none"> 1. Barbed stitch/Vloc 2. Fibrin glue/sealants (Tisseel, Evicel) 3. Gelatin thrombin agents (Flo seal, Surgiflo) 4. Oxidized cellulose polymer (Surgicel, Surgifoam) 5. Hemostatic patch (Hemopatch) 6. Bolster 7. Placing clips over knot tying 8. Re-approximation of Gerota’s fascia 9. Placement of a drain <p>Newly suggested:</p> <ul style="list-style-type: none"> • Early unclamping and suture ligate arterial bleeders

Bold indicates agreement/approval of the principle for next round.

Supplementary Table 1B. Truncated responses round 1

Truncated response	Reasoning
<p>Prior to tumor resection:</p> <p>“Consideration of use of bulldog clamps if hilar anatomy demonstrates multiple vessels. Use of en-bloc clamp may not occlude multiple arteries, while allowing the vein to be clamped”</p> <p>“Ensuring good correlation between computed tomography findings of number of vessels and intraoperative findings”</p>	<p>Summarized within existing principles</p>
<p>During tumor resection:</p> <p>“Running suture layer of the base layer”</p>	<p>Captured within “during renorrhaphy”</p>
<p>During renorrhaphy:</p> <p>“Technique of suturing should be mastered”</p> <p>“Two-layer closure with barbed suture, when possible”</p> <p>“Don’t place parenchymal (first layer) sutures too deep (can hit larger vessels)”</p> <p>“Use of hemostatic agents should be PRN only”</p> <p>“Lysine analogs”</p> <p>“Bringing cortex together. Not putting surgicel in the defect.”</p> <p>“Horizontal mattress closure”</p>	<p>Summarized within existing principles or excluded as within basic surgical skills</p>

Prior to tumor resection	During tumor resection	During renorrhaphy
<ol style="list-style-type: none"> 1. Clamping artery + vein vs. artery alone 2. Discontinuation of anti-platelet agents 3. Renal mobilization and hilar dissection 4. Selective arterial clamping 5. Adequate pneumoperitoneum 6. Prior suture preparation <p>Newly suggested:</p> <ul style="list-style-type: none"> • Robotic – ensure trocars/tract visible if instrument change needed • Having gelatin based sealant ready • Having Vloc ready 	<ol style="list-style-type: none"> 1. Enucleation 2. Early clipping of vessels 3. Reducing resection margin to tumor (staying close to tumor) 4. Increasing pneumoperitoneum 5. Assistant to apply pressure 6. Unclamping vein if bleeding <p>Modification to existing:</p> <ul style="list-style-type: none"> • Apply pressure to bleeding sites 	<ol style="list-style-type: none"> 1. Barbed stitch/Vloc 2. Gelatin thrombin agents (Flo seal, Surgiflo) 3. Placing clips over knot tying 4. Re-approximation of Gerota’s 5. Placement of a drain 6. Early unclamping and suture ligate arterial bleeders <p>Newly suggested: N/A</p>

Bold indicates agreement/approval of the principle for next round.

Truncated response	Reasoning
<p>Prior to tumor resection:</p> <p>“Satinsky if heminephrectomy, selective artery alone for small amenable lesions, artery alone for non-complex cases”</p>	Summarized within existing principles
<p>During tumor resection:</p> <p>“Pressure on the parenchyma with an instrument the surgeon controls”</p> <p>“Placing two bulldogs on artery”</p>	Summarized within existing principles
<p>During renorrhaphy:</p> <p>“Reduce pneumoperitoneum and bring BP to normal to ‘test’ closure before finishing”</p> <p>“Oversee collecting system separately from other stitches”</p>	Summarized within existing principles or excluded as within basic surgical skills